FDA 510(k) Premarket Notification

K022641 TOKUYAMA REBASE II

CLEARED

Oct 2, 2002
55 days to decision

K022641 · Product code: **EBI** · Dental
Source: https://www.510kdatabase.net/k022641/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Aug 8, 2002
Decision date	Oct 2, 2002
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Tokuyama America, Inc.**
Location	Washington, DC, US
Contact	DANIEL J MANELLI
510(k) history	22 submissions · 22 cleared · 1990-2002